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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,054	06/28/2000	Maryvonne Chariot	P62285US1	6768

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER
BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/605,054	Applicant(s) CHARIOT ET AL.	
	Examiner Alysia Berman	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/125840* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2002 has been entered.

Claims 29 and 31 have been amended. Claims 21-43 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 22, 24-26, 30-34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with the HCAPLUS abstract of Desager et al., *Pharmacokinetic-pharmacodynamic relationships of H1-antihistamines*, Clin. Pharmacokinet. (1995) 28(5):419-32.

This rejection is maintained. US '062 discloses a controlled and continuous release dosage form containing a matrix made from a fatty acid material, a neutral lipid or, preferably, a combination of both (abstract and col. 3, lines 43-45). Coated tablets are taught at column 1, lines 51-53. The matrix is made of an admixture of a fatty acid consisting of 12-28 carbon atoms such as stearic acid and palmitic acid (organic acids) and a neutral lipid such as stearin, palmitin, castorwax (hydrogenated castor oil) and glycerides (col. 3, lines 19-44). See also column 7, line 43 to column 8, line 10 for fatty acids, lecithin and hydrogenated castor oil. US '062 teaches that antihistamines are suitable biologically active materials for use in the dosage forms. (col. 5, line 16).

US '062 teaches that the percentage of components in the formulation can be varied to modify the controlled release rate of the active agent (col. 3, lines 56-60). Varying the percentages of components would inherently vary the weight ratios of components and the specific amounts of components. US '062 does not teach the antihistamine mizolastine. Desager et al. teach that mizolastine is an effective antihistamine that does not cause drowsiness.

The combination of the prior art teaches a composition that contains the same components as instantly claimed. One of ordinary skill in the art would expect a composition containing the same components to exhibit the same properties, i.e. pH

independent dissolution profile, an *in vivo* mizolastine release that prevents any plasma peak and a mizolastine bioavailability that is not decreased relative to that of an immediate release formulation. Burden is shifted to Applicant to show that the compositions of the prior art do not exhibit the instantly claimed properties. Additionally, because it is considered within the skill in the art to adjust the parameters of materials in order to achieve optimal effects, these limitations are not given patentable weight absent evidence of unexpected results.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicant's functional language at the point of novelty does not render the claims patentable over the prior art absent evidence that the prior art compositions do not exhibit the functionality claimed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '062 and substitute mizolastine of Desager

et al. for the antihistamine expecting to obtain a controlled and continued release antihistamine tablet that does not cause drowsiness.

Claims 23, 27-29, 35-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with Desager et al. as applied to claims 21, 22, 24-26, 30-34, 38 and 39 above, and further in view of US 5,102,666 (666).

This rejection is maintained. US '062 and Desager et al. teach all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. Neither reference teaches the organic acids of claims 23, 27-29, 35-37 and 39-43, specifically L-tartaric acid. US '666 teaches that tartaric acid can be added to controlled release tablets containing antihistamines for flavoring and breath freshening.

US '666 encompasses both a racemic mixture and any individual isomers of tartaric acid. Nothing unobvious is seen in substituting one isomer for another or for the racemic mixture. One of ordinary skill in the art would expect that structurally similar isomers would exhibit similar properties. Therefore, absent evidence of unexpected results, the limitation of the L-isomer of tartaric acid does not render the claims patentable over the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '062 and Desager et al. and add tartaric acid as taught by US '666 expecting to obtain a controlled release antihistamine tablet with a pleasant taste and breath freshening properties.

Response to Arguments

Applicant's arguments filed August 27, 2002 have been fully considered but they are not persuasive.

In response to Applicant's request that the Examiner point out on the record how each of the current criteria is satisfied for each rejected claim by each combination of references, the Examiner's burden under 35 U.S.C. 103 has been met in the above rejections. Additionally, Applicant refers to Figures 1 and 2 of the instant application. However, no figures were found in the instant application as filed.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to use mizolastine as taught by Desager et al. in the composition of US '062 is found in the teaching of Desager et al. that mizolastine is an antihistamine that does not cause drowsiness. One of ordinary skill in the art would be motivated to use mizolastine as taught by Desager et al. as the antihistamine in the composition of US '062 expecting to obtain a sustained release antihistamine medicament that does not cause drowsiness. The motivation to use tartaric acid as taught by US '666 in the composition obtained by

the combination of US '062 and Desager et al. comes from the teaching of US '666 that tartaric acid provides breath freshening and flavoring to oral drug delivery systems.

Claim 21, which is limited by the phrase "consisting essentially of", only excludes those components that would material effect the nature of the instant invention. Applicant has not provided evidence that any of the required components of the composition of US '062 would materially effect the nature of the composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Alysia Berman
Patent Examiner
November 25, 2002